REMARKS

The Examiner is thanked for his careful review of the specification. There is indeed a typographical mistake on page 10, line 34 in which Figure 8 is incorrect. Instead, this should read "Figure 6". The specification has been amended accordingly.

Claim 1 has been amended to recite the bacterial strain in italics.

Rejection under 35 USC 102(b)

The Examiner has rejected claims 1 and 3 as anticipated by Tauch et al. The Tauch references describes the genetic organization of the large resistance plasmid pTP10 and the presence of a transposon associated with chloramphenicol resistance. Tauch et al describe how the sequence of the plasmid from *C.striatum* contains a number of open reading frames of unknown function encoding hypothetical proteins. No function was ascribed to the open reading frames and no teaching was provided for isolating the hypothetical proteins or the genes encoding them. No motivation was provided to clone any of the hypothetical proteins and no assays were suggested to achieve the same.

In the present application, Claim 1 requires an isolated DNA coding for the CstMI restriction enzyme, wherein the isolated DNA is obtainable from *Corynebacterium striatum.* Claim 3 requires that the

isolated DNA is obtainable from ATCC Accession No. PTA-5291 referring to a foreign host cell.

Tauch does not describe an isolated DNA coding for a functional protein. In fact, Tauch only describes a sequence in a genome (native plasmid). Moreover, the Tauch reference is not enabled for obtaining the sequence in the form of an isolated DNA capable of expressing a protein of known function.

In general, an isolated DNA (a gene) encoding a particular protein can only be verified if the DNA is cloned and expressed. Absent expression, there can be no certainty that the gene has been isolated.

Protein expression can be determined using an assay that detects a property of the protein. Tauch does not suggest a possible function or distinguishing property for the hypothetical proteins encoded by the DNA sequence. Indeed, the reference did not even minimally seek any sequence homology between the genomic DNA encoding the hypothetical protein and genes with known functions in a database of genes.

It was only when applicants sought to find enzymes related to MmeI that they identified a CstI DNA sequence, which interestingly coded for a novel enzyme with a substantially different recognition site from MmeI. This provided the motivation to clone the CstMI restriction endonuclease gene and to obtain it in an isolated form.

The Examiner is aware from his extensive experience evaluating inventions relating to restriction endonucleases that it is not generally possible to clone a gene expressing a restriction endonuclease in a foreign host cell without additional methylase protection of the foreign host genomic DNA. This requires a knowledge of the appropriate methylase capable of methylating bases at the restriction endonuclease cleavage site and then identifying and cloning the methylase in addition to the restriction endonuclease. Furthermore, the methylase must be sufficiently active to protect all target sites in the host genome. This requires regulating methylase expression in the host cell by cloning the methylase gene in a vector containing a suitable promoter. Applicants conducted significant experimentation to determine that the methylase and endonuclease activity were contained in a single gene and how to express both proteins in the appropriate amounts to maintain cell viability. Significant amounts of experimentation were further required to determine the cleavage site of the enzyme expressed by the isolated DNA so as to establish an assay to prove that the isolated DNA with the claimed function had been obtained (see Examples).

In summary, the Tauch reference does not describe or enable the claimed invention and therefore cannot be anticipatory under 35USC 102(b). Applicants respectfully request that the rejection be reversed.

Rejection under 35 USC 103

The Examiner has rejected claims 1-5 as unpatentable over Tauch et al. (AD) in light of Tauch et al (U). The basis of this rejection is that it would have been obvious to place the DNA into a vector or host cell.

Applicants assert that there is no motivation to isolate the gene for the hypothetical protein from its native context (the entire genome) in any of the three cited reference or in the combined references. Nor would it have been possible to obtain an isolated DNA encoding a restriction endonuclease as required in the claims from the description in the cited references because of the lack of a description of a suitable assay. Hence the Examiner is requested to reverse the current rejection.

Claim 6 has been amended to place it in a condition for allowance.

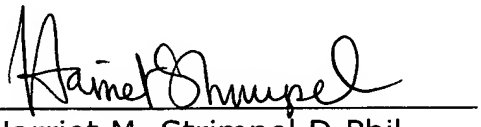
CONCLUSION

For the reasons set forth above, Applicants respectfully submit that this case is in condition for immediate allowance. Early and favorable consideration leading to prompt issuance of this Application is earnestly solicited.

Applicants petition for a three-month extension of time and submit check in the amount of $ 510 to cover the fees. Please charge any deficiencies to Deposit Account No. 14-0740.

Respectfully submitted,

NEW ENGLAND BIOLABS, INC.



Date: April 7, 2006

Customer No.: 28986

Harriet M. Strimpel D.Phil.
(Reg. No.: 37,008)
Attorney for Applicants
240 County Road
Ipswich, MA 01938-2723
(978) 380-7373